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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/618,444 | 07/11/2003 | Julie K. Andersen | 314-300710US | 4209 |

22798 7590 08/10/2005

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

| EXAMINER | |
|---|---|
| KOLKER, DANIEL E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1649 | |

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/618,444 | ANDERSEN, JULIE K. | |
| | Examiner | Art Unit | |
| | Daniel Kolker | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *11 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claim 73 depends from claim 78, as written, but appears to depend from claim 72. For the purposes of restriction, the examiner has assumed that claim 73 depends from claim 72.

2. Claim 93 depends from claim 39, but appears to depend from claim 92. For the purposes of restriction, the examiner has assumed that claim 93 depends from claim 92.

Appropriate clarification is requested.

### *Election/Restrictions*

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 34, 35 – 36 (in part), 37 – 38, 40 – 66, drawn to methods of inhibiting neural degeneration or onset or progression of disease by administering agents to mammals or contacting agents with iron, classified in class 514, subclass 12 or 169, for example.

II. Claims 35 – 36 (in part) and 39, drawn to administering an agent that upregulates expression of an endogenous iron chelator, classification dependent upon structure.

III. Claims 67 – 69 (in part) 70-71, 74 – 76 (in part) and 77 - 78 drawn to kits and pharmaceutical compositions comprising nucleic acid, classified in class 514, subclass 44, for example.

IV. Claims 67 – 69 (in part) 72 - 73, and 74 – 76 (in part) drawn to kits and pharmaceutical compositions comprising iron chelators, classified in class 514, subclass 169, for example.

V. Claims 79 – 80 (in part), 81 – 82, and 89-91 (in part), drawn to neural tissue in contact with iron chelators, classified in class 435, subclass 368, for example.

VI. Claims 79 – 80 (in part) 83 – 88, and 89-91 (in part), drawn to neural tissue in contact with protein, classified in class 435, subclass 368, for example.

VII. Claims 92 - 93, drawn to methods of evaluating the risk or progression of a disease, classified in class 436, subclass 84, for example.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case

the different inventions are drawn to methods of either administering or contacting iron with small organic molecules, proteins, or agents that upregulate expression of endogenous iron chelators. The methods require different starting materials and thus are patentably distinct. Furthermore searches for the methods are not expected to be coextensive. Consideration of group I requires search of specific organic molecules; consideration of group II requires search for compounds, not limited by structure, which have certain functions and those functions would not be expected to be properties of the small organic molecules or proteins of group I. Because these searches are not coextensive, consideration of groups I and II together would present a serious burden for the examiner.

Inventions I and II are not related to invention III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together. Inventions I and II are drawn to methods of administering or contacting iron with small molecules, protein, or agents which upregulate expression of endogenous chelators, none of which are nucleic acid. Invention III is drawn to kits comprising nucleic acid, which cannot be used in the methods of groups I and II. Therefore the inventions are patentably distinct. Furthermore search for nucleic acids would not be informative as to the patentability of the methods of groups I and II. Therefore consideration of group III with either group I or group II would present a serious burden for the examiner.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case desferrioxamine, one of the products of group IV, can be used cell proliferation in vascular smooth muscle. Furthermore search for the products and kits comprising them would not be informative as to the patentability of the methods of using them. Therefore consideration of group IV with group I would present a serious burden for the examiner.

Inventions I and II are not related to any of Inventions V – VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case groups I and II are drawn to methods of administering or contacting iron with

specific groups of molecules. Inventions V and VI are drawn to tissue in contact with agents, but do not require the administration or contacting step; they are drawn to compositions of matter. Invention VII is drawn to a different method with different steps. Searches for the compositions of groups V and VI, or for the method of group VII would not be informative as to the patentability of the methods of Groups I and II therefore considering either of groups I or II with any of group V – VII would present a serious burden for the examiner.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group II is drawn to methods of administering agents which upregulate the expression of endogenous chelators, whereas group IV is drawn to exogenous molecules which are iron chelators. The methods of group II cannot be accomplished by administering the agents from the kits of group IV. Furthermore search for the agents of group IV would not be coextensive with search for methods of administering other agents and thus there would be a serious burden if group IV were to be examined with group II.

Inventions III – VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case groups III and IV are drawn to kits comprising nucleic acid and iron chelators, respectively. Groups V and VI are drawn to compositions comprising neural tissue, which is not required for the kits of groups III and IV. Therefore groups III and IV are not related to either of groups V or VI. Group III requires a nucleic acid, which is not required for any of groups IV – VI. Groups V and VI both require neural tissue, but group I requires iron chelators, which are not required for group VI, and group VI requires protein, which is not required for group V. Searches for these groups would not be coextensive as the products, kits, and neural tissues in contact with agents all require different patentably distinct materials. Therefore consideration of any of groups III – VI together would present a serious burden for the examiner.

Invention VII is not related to any of Inventions III – VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of group VII requires detection of free iron. Groups III – VI are drawn to products, which cannot be used in the methods of group VII. Search for any of the products of

groups III – VI would not be informative as to the novelty of the method of group VII, so there would be serious burden if any of groups III – VI were to be considered with group VII.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Requirement for Election of Species Within Groups I, and IV-VI***

6. If applicant elects any of groups I, or IV – VI for prosecution on the merits, election of a single species of agent is required.

This application contains claims directed to the following patentably distinct species of the claimed invention:

a) 5-chloro-7-iodo-hydroxyquinoline (clioquinol)

b) deferiprone

c) desferrioxamine

d) pseudan

e) ferritin

f) ferritin heavy subunit

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 – 3, 5 – 8, 11 - 22, 24, 27 – 37, 39 – 41, 44 - 54, 56, 59 – 72, 74 – 77, 79 - 81, 83, and 86 – 93 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species

to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
August 4, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
8-5-05